REMARKS/ARGUMENTS

Upon entry of this Preliminary Amendment into the above-identified Continuing Application, claims 1-17 will be under active consideration in the application.

The present Continuing Examination Application has been filed in response to the Final Official Action mailed on May 5, 2003. In the Final Official Action, the Examiner has rejected claims 1-16 under 35 U.S.C. 103(a) in view of the combination of U.S. Patent No. 6,370,511, issued to Dang with U.S. Patent No. 6,277,071, issued to Hennessey et al. In response to Applicant's Amendment filed February 24, 2003, the Examiner has taken the position that Applicant did not point to any specific distinction between the features disclosed in Dang and Hennessy and the features that are presently claimed. Applicant respectfully submits that the Examiner has erred in his review of Applicant's previously submitted Amendment, and in his characterization of the Hennessy reference. Applicant has amended claims 1, 9, and 15, and added new claim 17 so as to more distinctly define the present invention.

Applicant once again respectfully submits that the Examiner has failed to establish a prima facie case of obviousness, since there is absolutely no suggestion or motivation existing in the Dang and Hennessey references, taken as a whole, of a computer-implemented method for assessing deviations from a preselected medical treatment that has been indicated by appropriate diagnosis from a clinician in which an alert notice to said clinician is issued at the time of performance of the clinical action identified as a variance from an identified

appropriate clinical pathway. At page 12 of the Final Official Action, the Examiner suggests that the issuance of a letter by Hennessy's system is some how suggestive of an alert notice being issued to a treating clinician at the time of performance. Applicant respectfully submits that the Examiner's characterization of Hennessy in this regard is incorrect, and relies upon hindsight knowledge of Applicant's invention.

More Particularly, Hennessy's method does not disclose or suggest, in anyway, the issuance of an alert notice for deviations from a standard course of treatment according to an accepted clinical pathway, at the time of performance of the clinical action.

For example, in Hennessy's Summary of the Invention, it is taught that:

". . . The test thresholds represent known parameters associated with the chronic disease, such as blood glucose, lipids, liver enzyme and microalbumin for the disease of diabetes. If the test threshold value derived from the guideline is exceeded, an alert sequence is activated, in which the patient is categorized as a high risk patient, the physician is notified, the patient is notified, the health care provider is notified, and the patient's treatment plan is altered to treat the high risk patient. . . . (col. 4, lines 31-37)

Hennessy simply states "the physician is notified", however, Hennessy does not teach or suggest in any way that the notification occur at the time of performance of the clinical action, a critical aspect of Applicants claimed method. (See, page 19, lines 11-16, of Applicant's specification.) Instead, Hennessy strongly suggests that the timing of the notification of a physician is of only minor import or to be done outside the actual clinical visitation. More importantly, Hennessy simply does not contemplate the clinician being given an opportunity

to alter their decision at the time of treatment. Referring to col. 5, lines 60-67 and col. 6, lines 3-6, Hennessy teaches:

". . .If a test result exceeds an expected threshold, an alert is generated and a notation is stored in risk manager 24. The alert may be communicated to an off site location 26, e.g. via e-mail 27, such as to an employer, health maintenance organization and the like, and/or a letter may be printed to the patient via printer 28. . . Provider information 30 (e.g., a physician) and health plan information 32 are also stored in central data base 12, to enable communication with medical providers and third parties. . . ."

Hennessy states that his alert is to be communicated to an off site location and not to the treating clinician, at bedside, at the time of performance of the clinical action. Here, Hennessy suggests that the notification to medical providers occurs after communication with a central database where the identities of such *medical providers and third parties*, may be determined. Contrary to the Examiner's assertions, this is a strong suggestion that such medical providers are not located at the patients bedside when the alert is issued, since their identities must first be ascertained in a database search! Moreover, such a system could not be said to offer the clinician the opportunity to alter their treatment decision since by the time the Hennessy alert is issued, the treatment has already been administered to the patient, *fait accompli*. This methodology could hardly be characterized as suggesting the issuance of an alert notice to a clinician for deviations from a standard course of treatment according to an accepted clinical pathway, at the time of performance of the clinical action. Moreover, it can not be said that Hennessy ever envisioned alerting a clinician for deviations from a standard course of treatment according

to an accepted clinical pathway, at the time of performance of the clinical action, when at col. 6, lines 66-67, col. 7, lines 1-2, and again at col. 9, lines 14-21 Hennessy contemplates his monitor making such alerts via letters and e-mail!

". . .Monitor 10 notifies providers, health care plans and patients via letters, e-mail, etc. Letters may be stored in the. . . form of reminders, and/or report letters, indicating test results, a missed appointment, an alert and the like. . . If the alert function has been selected in the patient record 16, an alert for the patient to alert the system manager and/or medical provider/physician of the event is registered. Also, the patient's name is added to the risk manager 24, a letter is generated to send to the patient (and/or another physician or caretaker), the information is communicated off site 26, such as to a health maintenance organization, provider, and the like. ."

Here, Hennessy states that it is the patient, not the system, that provides an alert to ". . . *the system manager and/or medical provider/physician of the event is registered. . .*" Then, as a secondary task, a letter directed to the patient's physician is generated for mailing. The Examiner appears to suggest that a letter some how ". . .corresponds to the claimed feature. . . ." This is simply incorrect. Letters (presumably with stamps, and to be deposited with the U. S. Postal Service) are hardly suggestive of an alert being given to a treating clinician at the time of performance of the clinical action, or providing the physician with the opportunity to alter their decision at the time of performance of the claimed action. Further indicative of Hennessy's lack of a suggestion of an immediate alert to a treating clinician at the time of performance of the clinical action, is the following description of the operation of their system at col. 10, lines 38-43:

". . .For the physician, the alerts are categorized by patient, date, test type, detail (goal, threshold, result). Reminders are also listed for the respective

physician, indicating the date created, schedule, patient name, author and the subject. . . ."

The Examiner is respectfully asked to consider why Hennessy would need to provide a treating physician with an alert letter that is ". . .*categorized by patient, date, test type*. . ."? Wouldn't the physician at least know the name of the person she is treating, the date and time of her treatment by, e.g., simply looking at her watch while she was treating her patient, and the treatment type! Applicant respectfully submits that the only reason for providing an alert letter with a date, time, test-type, and patient name is because Hennessy does not envision the alert being given to the treating clinician at the time of performance of the clinical action.

Taken as a whole, Dang and Hennessy teach methods for utilizing healthcare insurance related data and clinician provided data to evaluate the cost efficiency, efficiency of past treatment, and to allow for planning for future treatment. Neither reference alone, nor their combination evenly vaguely suggests an automatically triggered alerting mechanism that is activated, in real time, during consultation at bedside, when a treatment is initiated by a treating physician that deviates from an expected or standard treatment thereby allowing the physician to alter their decision. Furthermore, the requisite motivation to combine these references is absent from them.

Since nothing in the prior art references would lead a person of ordinary skill in the art to formulate a method like that described in the application, or defined by claims 1 - 17, it once again appears that hindsight knowledge of the

present invention is the only motivation to combine these references. The Federal Circuit has held that the PTO commits error when rejecting a claimed invention as an obvious combination of the teachings of two prior art references when the prior art provided no teaching, suggestion, or incentive supporting the combination. See also, Northern Telecom, Inc. v. Datapoint Corp., 15 U.S.P.Q. 2d 1321, 1323; In re Geiger, 2 U.S.P.Q. 2d 1276, 1278.

Claims 1-17 are allowable for all of the foregoing reasons.

Accordingly, Applicant respectfully requests the issuance of a Notice of Allowability for this case. Early and favorable consideration is respectfully requested.

If a telephone conference would be of assistance in advancing prosecution of the above-identified application, Applicant's undersigned Attorney invites the Examiner to telephone him at **717-237-5516**.

Respectfully submitted,

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